Application No.: 10/664,225 8 Docket No.: 514862000700 Response to Final Office Action of 1/30/2008

# REMARKS

Claims 1-16, 18-27, and 29 were pending in the present application. Claims 1-3, 23, 26, and 29 have been amended. Claim 10 has been canceled. Claims 30 and 31 are newly presented. Claims 1-16, 18-27, and 29-30 remain pending in the present application.

The amendments to the claims and the new claims are supported by the specification and claims, as originally filed. No new subject matter has been added.

Summary of Examiner Interview of March 27, 2008

Applicant thanks the Examiner for the courtesy of the telephonic interview conducted on March 27, 2008 with the undersigned. Claims 1 and 6, and EP 0904729 were discussed. Applicant believes that agreement was reached with respect to vacating the 35 USC 112 indefiniteness rejection of claim 6, in light of remarks consistent with those made below. Applicant further believes that agreement was reached with respect to the applicability of 35 USC 112, sixth paragraph, to the "means for feeding the sample of the exhalation air from the buffer chamber to the NO sensor at a suitable flow rate for the NO sensor, wherein the suitable flow rate for the NO sensor is lower than the exhalation flow rate" element of claim 1. Agreement was also reached that application of the sixth paragraph would require the cited art to disclose the claimed function. Applicant agreed to present an argument as to why EP 0904729 does not disclose a device having the claimed function(s).

Claim Rejections- 35 USC § 112

Claim 2, 6-9, and 26 were rejected under 35 USC § 112, second paragraph, as being indefinite.

# Claim 2

Claim 2 was rejected for failing to further limit the position of the flow regulator. The Examiner further indicated that the relationship of the flow regulator to the scrubber was not further Application No.: 10/664,225 9 Docket No.: 514862000700

Response to Final Office Action of 1/30/2008

defined. Claim 2 has been amended to further limit the flow regulator to a regulator connected to the buffer chamber and configured to provide a flow rate of 20-800 ml/s. Applicant respectfully asserts that claim 2, as amended, further limits claim 1 and is distinct. Applicant further asserts that distinctness does not require specific provision of the relationship between the flow regulator and the scrubber.

## Claim 6-9

Claim 6 and claims 7-9, which depend from claim 6, were rejected for failing to make clear what type of "control electronics" is intended to verify the parameters and control exhalation.

35 USC § 112, second paragraph, requires that the language of the claim "apprises one of skill in the art of its scope" so that one of skill in the art could interpret "the metes and bounds of the claims so as to understand how to avoid infringement." MPEP 2173.02. Given the language of the claims, one of skill would be able to distinguish between control electronics capable of performing the recited functions and those control electronics not capable of performing the recited functions.

Accordingly, assuming the existence of all other claimed elements, one of skill would be able to distinguish the metes and bounds of claims 6-9 so as to determine whether a given device is infringing based on the specific control electronics, if any, of the device.

#### Claim 10

Claim 10 was rejected for use of the terms "long" and "small." Claim 10 has been canceled, rendering the rejection moot.

## Claim 26

Claim 26 was rejected as indefinite for failing to state that the data is entered into the user interface. The Examiner suggested that the addition of language clarifying that the data is entered into the user interface would vacate the rejection. Applicant thanks the Examiner for the guidance and has so amended the claim.

Application No.: 10/664,225 10 Docket No.: 514862000700

Response to Final Office Action of 1/30/2008

For at least the reasons stated above, Applicant respectfully requests that the rejections of claims 2, 6-9, and 26 under 35 USC § 112 be withdrawn.

Claim Rejections- 35 USC § 103

Claims 1-13 and 18-23

Claims 1-13 and 18-23 were rejected under 35 USC § 103(a) as being unpatentable over EP 0904729 (hereinafter the "EP publication") in view of USP 7,045,359 (hereinafter "Birks").

As an initial matter, Applicant notes that the Examiner has not signaled that claim 1 contains a limitation under 35 USC 112, sixth paragraph, namely "means for feeding the sample of the exhalation air from the buffer chamber to the NO sensor at a suitable flow rate for the NO sensor, wherein the suitable flow rate for the NO sensor is lower than the exhalation flow rate" (hereinafter the "means for feeding limitation"). See MPEP 2181 ("Where a claim limitation meets the 3-prong analysis and is being treated under 35 U.S.C. 112, sixth paragraph, the examiner will include a statement in the Office action that the claim limitation is being treated under 35 U.S.C. 112, sixth paragraph."). Applicant submits and requests that the limitation be treated under 35 U.S.C. 112, sixth paragraph.

Applicant notes that the Examiner stated that "[t]he pending apparatus claims contain the new limitations '...wherein said suitable flow rate for the sensor is lower than the exhalation flow rate' which does not specify any structural limitations and appears to be a method of intended use of an apparatus which is of no patentable moment with respect to the pending apparatus claims."

Office Action mailed January 3, 2008 at page 5-6, bridging paragraph. Applicant respectfully asserts that the Examiner's statement fails to take into account the limitation under 35 U.S.C. 112, sixth paragraph. The cited limitation clarifies the function to be performed by the claimed means and should therefore be compared to the prior art.

The Examiner indicated that the combination of the check valves and the regulator switch of the EP publication reads on the "pressure regulators." Office Action mailed January 3,

Application No.: 10/664,225 11 Docket No.: 514862000700 Response to Final Office Action of 1/30/2008

2008 at page 3. By pressure regulators, Applicant presumes the Examiner is referring to the "flow regulator" element and the means for feeding limitation.

The combination of the check valves and the switch of the EP Publication does not read on at least the means for feeding limitation of claim 1, from which rejected claims 2-13 and 18 depend. To apply prior art to a 35 U.S.C. 112, sixth paragraph limitation, "requires that the prior art element perform the identical function specified in the claim." See MPEP 2182 and 2183. The EP publication does not disclose any structure that performs the specified function of the means for feeding limitation. The Examiner makes the following statement, which Applicant believes is directed to the means for feeding limitation: "[a]dditionally, the claimed limitations specifying the flow of the gas and/or feedback to the patient, the Office maintains EP has the appropriate means to accomplish all of these functions." Office Action mailed January 3, 2008 at page 3. Applicant asserts that the requirement is not for the prior art to disclose means that may accomplish the recited functions. Rather, the requirement is more precise in requiring that the prior art disclose an element that actual "performs the function specified in the claim." See MPEP 2183 (stating the requirements for a prima facie case of equivalence to a 35 U.S.C. 112, sixth paragraph limitation).

In summary, Applicant asserts that the EP publication and Birks, individually or in combination, do not teach or suggest an element with the required function of "feeding the sample of the exhalation air from the buffer chamber to the NO sensor at a suitable flow rate for the NO sensor, wherein the suitable flow rate for the NO sensor is lower than the exhalation flow rate." Additionally, in the context of an obviousness determination, the EP publication teaches away from an element with the recited function. As stated in the previous response, the EP publication is primarily focused on converting all of NO to NO<sub>2</sub> by increasing the pressure throughout the system and specifically prior to introduction of sample to the sensor. See MPEP 2141.02(VI) ("A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention."). Applicant respectfully requests that the Examiner reconsider Applicant's remarks of October 18, 2007, regarding the EP publication in view of the requirements of 35 U.S.C. 112, sixth paragraph.

Response to Final Office Action of 1/30/2008

Method claims 19-23 contain a similar limitation: "an NO concentration is determined in said sample, wherein the flow rate suitable for said sensor is lower than the exhalation flow rate." Applicant asserts that the EP publication and Birks, individually or in combination, do not teach or suggest this limitation of claims 19-23.

For the reasons stated above, Applicant requests that the rejections of claims 1-13 and 18-23 under 35 USC § 103(a) be withdrawn.

## Claims 14-15, 26-27, and 29

Claims 14-15, 26-27, and 29 were rejected under 35 USC § 103(a) as being unpatentable over the EP publication in view of Birks and further in view of USP 6,039,251 (hereinafter "Holowko"). Claims 14, 15, and 29 depend from claim 1. Method claim 29 also contains the limitation of claim 19 discussed above. Claims 26-27 depend from claim 19.

Holowko does not address the deficiencies discussed above with respect to the combination of the EP publication and Birks. Accordingly, Applicant asserts that the EP publication, Birks, and Holowko, individually or in combination, do not teach or suggest all the limitations of the rejected claims.

Applicant respectfully requests that the rejections of claims 14-15, 26-27, and 29 under 35 USC \$ 103(a) be withdrawn.

Application No.: 10/664,225 13 Docket No.: 514862000700 Response to Final Office Action of 1/30/2008

# Claims 16 and 24

Claims 16 and 24 were rejected under 35 USC § 103(a) as being unpatentable over the EP publication in view of Birks and further in view of USP 3,925,183 (hereinafter "Oswin"). Claim 16 depends from claim 1. Claim 24 depends from claim 19.

Oswin does not address the deficiencies discussed above with respect to the combination of the EP publication and Birks. Accordingly, Applicant asserts that the EP publication, Birks, and Oswin, individually or in combination, do not teach or suggest all the limitations of the rejected claims.

Applicant respectfully requests that the rejections of claims 16 and 24 under 35 USC § 103(a) be withdrawn.

Application No.: 10/664,225 14 Docket No.: 514862000700 Response to Final Office Action of 1/30/2008

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to <a href="Deposit Account No.: 03-1952">Deposit Account No.: 03-1952</a> referencing <a href="Deposit Account No.: 514862000700">Deposit Account No.: 514862000700</a>. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 28, 2008 Respectfully submitted,

Examiner is invited to telephone the undersigned at the number given below,

By: /Brian B. Ho/ Brian B. Ho

Registration No.: 60,199

MORRISON & FOERSTER LLP 425 Market Street San Francisco, California 94105-2482

Telephone: (415) 268-7624 Facsimile: (415) 268-7522